

GAO

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Report to the Ranking Minority Member,
Subcommittee on International
Economic Policy and Trade, Committee
on Foreign Affairs, House of
Representatives

July 1992

FOOD SAFETY AND QUALITY

FDA Can Improve Monitoring of Imported Cheese



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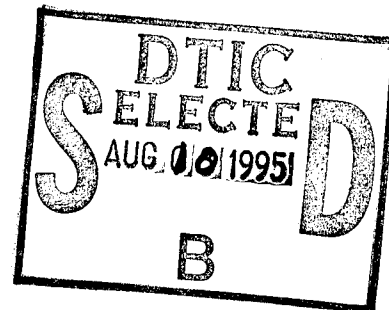
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Resources, Community, and
Economic Development Division

B-248754

July 6, 1992

The Honorable Toby Roth
Ranking Minority Member
Subcommittee on International
Economic Policy and Trade
Committee on Foreign Affairs
House of Representatives



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Dear Mr. Roth:

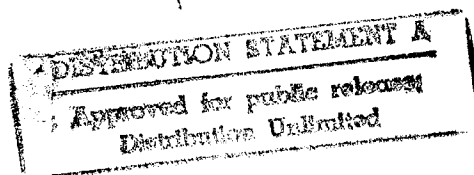
The Food and Drug Administration (FDA) is responsible for ensuring the safety of domestic and imported food products except for meat and poultry, which are the responsibility of the U.S. Department of Agriculture. The growing volume and the variety of food imported into the United States during the last few years, without a corresponding increase in FDA's import resources, have led to growing concerns about FDA's ability to adequately protect American consumers from unsafe imported foods. In an August 29, 1991, letter, you expressed concerns about recent FDA detentions of imported cheese contaminated with pathogens and other harmful substances. As agreed with your office, we reviewed (1) the health risks presented by imported cheeses, especially soft cheese; (2) FDA's efforts to prevent the import of unsafe cheese, including the effectiveness of the French certification program for soft cheese; and (3) the concerns about FDA's import program that we identified in the past and are relevant to imported cheese.

Results in Brief

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Food Safety and
Quality. FDA Can
Improve Monitoring
of Imported Cheese

FDA categorizes cheeses, especially soft and semi-soft styles, such as Brie and Camembert, as high-risk food products because they are susceptible to contamination by potentially fatal bacteria, such as *Listeria monocytogenes* (hereinafter referred to as *listeria*) and *salmonella*. About one-third of all cheeses imported into the United States are of the soft and semi-soft variety. Moreover, products from some exporting countries, which do not have food safety standards similar to those in the United States, have had a higher incidence of bacteriological contamination than other countries and have been refused entry more frequently. To better regulate the safety of imported soft cheeses, FDA has worked with exporting countries, such as France and Italy, whose cheese products have had higher violation rates, to develop certification programs. FDA has implemented a certification program with France under which the French government inspects cheese manufacturing facilities exporting to the



United States and certifies that the facilities are listeria-free. However, FDA has not formally monitored the program and does not have sufficient data to determine the program's effectiveness.

FDA relies primarily on end-product inspections at U.S. points of entry to ensure the safety of imported foods, including cheese. In the past we reported on a number of problems with FDA's inspection procedures for imported foods. Some of these problems—such as FDA's low rates of sampling imports for contamination and other safety standards—are also relevant to imported cheese. For example, even though FDA's 3-percent sampling rate for imported cheese is 50 percent more than FDA's 2-percent sampling rate for all food imports, it may not provide adequate inspection coverage. Samples are not randomly selected and may not be representative of all imported cheese products. Given this situation and FDA's low level of sampling, comprehensive monitoring of certification programs becomes even more critical.

Background

Since 1985 the United States has annually imported an average of 290 million pounds of cheese valued at about \$390 million. The largest exporters of cheese to the United States are Italy, France, Denmark, New Zealand, Finland, and the Netherlands. These countries produce about 60 percent of the cheese imported into the United States.

Under the federal Food, Drug, and Cosmetic Act, FDA is responsible for ensuring that imported FDA-regulated food products, including cheese, meet the same safety and labeling standards as domestically produced food products. These standards require that imported foods be pure, wholesome, and accurately labeled. However, while FDA can inspect domestic food manufacturing or processing facilities, it does not have authority over, and therefore does not inspect, foreign food facilities. To ensure that imported foods meet domestic food standards, FDA relies primarily on testing and inspecting imported food products when they are offered for entry into the United States.

FDA's Center for Food Safety and Applied Nutrition is responsible for providing guidance to district offices and monitoring imported food products. FDA's district offices are responsible for conducting import inspections at various points of entry across the country. About 75 percent of all imported cheese shipments enter the United States through FDA's New York district.

Initially, FDA's district inspectors conduct a limited paperwork review of all import entries, including cheese shipments. This review helps FDA determine whether to release an entry or examine it further. If additional examination is warranted, it may consist of a (1) more detailed paperwork examination; (2) wharf examination, which is a quick, visual examination of the product;¹ or (3) physical examination, which includes a sample collection and laboratory analysis of the product. Products that appear to be in violation of U.S. standards, as identified by an FDA examination or otherwise, are detained and must be exported, destroyed, or reconditioned to bring them into compliance with U.S. laws and regulations.

According to FDA officials, inspections and sampling are targeted, on the basis of an inspector's knowledge and judgment, to those products or importers that have a history of violations. Problem commodities and/or importers are identified through import alerts issued to all FDA districts. Import alerts provide information to inspectors on products that may not conform to U.S. standards and that should be inspected. Imported products or importers that consistently violate U.S. standards may also be placed on automatic detention, which allows districts to detain the product without sampling or analysis. Through automatic detention, FDA shifts the burden of proving that a product is safe to the importer. The importer must provide FDA with an acceptable laboratory analysis, certifying that the detained product meets FDA's requirements or otherwise overcomes the appearance of a violation, before it is released for distribution in the United States.

Cheese Is Susceptible to Microbiological Contamination

Cheese is generally considered by FDA and the scientific community to be a high-risk food because it is susceptible to microbiological contamination. Salmonella, listeria, and enteropathogenic *Escherichia coli* (*E. coli*) are three high-risk pathogens associated with cheese. Foods contaminated with any of these three pathogens have been known to cause severe illnesses, especially in children, the elderly, and those with weakened immune systems. For example, foods contaminated with the listeria bacteria alone cause an estimated 1,850 cases of severe illness annually in the United States; about one-fourth of the illnesses result in death, according to the Centers for Disease Control.

Soft, semi-soft, and surface-ripened cheese (such as Brie and Camembert) or other types of cheese made from unpasteurized milk are highly

¹According to FDA officials, wharf examinations can alert inspectors only to clearly visible defects in the product, such as improper labeling and filth.

susceptible to microbial contamination because of their high moisture content and potentially high levels of bacteria. About 35 percent of all cheese imported to the United States is a soft or semi-soft type. Other cheeses, such as those with a high salt content, hard cheeses, and cheese made from pasteurized milk, are not as susceptible to microbial contamination because their ingredients and manufacturing processes inhibit bacterial growth.

The Centers for Disease Control has documented two outbreaks of illness caused by cheese imported into the United States. Both outbreaks, in 1971 and 1983, were caused by French cheese contaminated with *E. coli*. However, these documented occurrences may not represent the true incidence of food-borne illness caused by imported cheese. It is generally accepted by the scientific community that only between 1 and 4 percent of food-borne illnesses in the United States are actually reported. Most people do not report food-borne illnesses unless they are ill enough to seek medical attention. Moreover, even when a food-borne illness is recognized, it is often difficult to isolate the food or pathogen responsible for the illness.

FDA's Efforts to Regulate Imported Cheese

According to FDA officials, the agency increased efforts to regulate the safety of domestic and imported cheese in 1985, when a domestically produced soft, Mexican-style cheese contaminated with listeria was implicated in 84 deaths and 150 illnesses in California. After the 1985 listeria outbreak, FDA conducted extensive testing of both domestic and imported soft cheeses. FDA collected 786 samples of imported soft cheese from 15 countries and found listeria and *E. coli* contamination and high phosphatase levels² in imported soft cheese from France, Italy, and the Federal Republic of Germany. Eight of the 15 countries had no violative samples, and three had violations for a single contaminant. As a result, in 1986 FDA placed all imported soft cheeses on import alert status (which is still in effect) and a number of soft cheeses from France on automatic detention.

In response to FDA's actions, the French and Italian governments proposed certification programs for testing cheese exported to the United States and for ensuring that it meets U.S. standards. However, only the French certification program was implemented. Because FDA and the Italian government were unable to reach an agreement on who would be

²High phosphatase levels may indicate inadequate pasteurization of milk.

responsible for the certification program in Italy,³ this program was not implemented.

Under the French Plant and Product Certification Program for Listeria Testing in Soft-Ripened Cheese and Goat Cheese Made From Pasteurized Milk, which became effective February 1987, the French government agreed to inspect cheese manufacturing plants exporting to the United States and to certify that they are listeria-free. The French government also agreed to regularly provide FDA with a current list of all plants certified under the program, as well as issue a health certificate to certified plants. These health certificates, which are issued to French cheese plants every 2 months as a result of the French government's monitoring and sampling of their products, accompany all shipments of cheese to the United States. FDA does not accept health certificates that are more than 6 months old or that do not state the minimum time and temperature schedule the plant uses to pasteurize milk. The French government does not require firms to use pasteurization time and temperature controls recognized as adequate in the United States. Therefore, the French government agreed to provide the time and temperature controls used by certified plants on the health certificates to allow FDA to enforce U.S. requirements at the point of entry.

Effectiveness of the French Certification Program Is Unknown

We could not determine the effectiveness of the French certification program because FDA does not maintain sufficient data on cheese imported under the program. Although FDA officials told us that they believe the French certification program is working very well and has reduced the incidence of listeria in French cheese, they could provide us with only limited information to support this belief.

According to FDA officials, districts that receive a large number of products under a certification agreement, such as the New York district for French cheese, are expected to collect and analyze samples of the products for auditing these agreements. According to New York district officials, audit samples of French cheese under the certification program have been collected on a regular basis since the program became effective in 1987. However, they could not provide us with data on the total number of audit samples collected from 1987 to 1990.

³The Italian government wanted FDA to negotiate the certification program with an Italian cheese industry association, which was unacceptable to FDA.

Our review of the data in FDA's national data base also indicates that FDA did not begin to distinguish between samples collected for auditing the certification program and other samples until fiscal year 1991. Therefore, until 1991 FDA had no way of knowing which samples of French cheese that it collected and analyzed represented cheese imported from facilities under the certification program.

In addition, because of inconsistencies in FDA's data bases, it is unclear how many audit samples were actually collected for fiscal year 1991. We found that three FDA data bases had three different totals for the number of French soft cheese audit samples collected that year. According to FDA's Program Oriented Data System, FDA tested 45 audit samples for the certification program in fiscal year 1991. One sample was found contaminated with listeria and was refused entry into the United States. According to the New York district's Import Sample Tracking System, for that same year the New York district alone collected 115 audit samples of French cheese, of which 2 were refused entry into the United States. However, data in FDA's Laboratory Management System indicate that the New York Regional Laboratory analyzed 215 French soft cheese samples in fiscal year 1991 for microbiological contamination and found 3 in violation of U.S. safety standards. According to FDA headquarters officials, all 215 samples represent audit samples under the certification program.

FDA officials believe that the incidence of microbial contamination in French cheese has reduced since the certification program became effective. However, they could not provide us with any data to support this belief, and our review of the data in the Laboratory Management System raises questions about the true incidence of microbial contamination in French cheese. According to the data we reviewed, the violation rates for microbial contamination in French cheese samples had not decreased but varied from 4 percent in fiscal year 1987 to 10 percent in fiscal year 1989 and 1 percent in fiscal year 1991. Because FDA's sampling decisions are targeted to products or importers with a history of violations and are not drawn randomly, these numbers may not represent an accurate estimate⁴ of violation rates for French cheese. However, they raise questions about the basis of FDA's belief that the certification program has reduced the incidence of microbiological contamination in French cheese.

⁴A sufficiently large random sample of French cheese under the certification program would yield a reliable estimate of the violation rate at a given confidence level. However, the agency's samples are nonrandom and relatively small in size. FDA's targeted sampling procedure attempts to select items more likely to be in violation and therefore may overstate the actual violation rate. Also, differences in violation rates could be influenced by how well inspectors target cheeses for review.

FDA Samples a Small Percentage of Imported Cheese

FDA samples about 2 percent of all imported food products under its jurisdiction and about 3 percent of all imported cheese offered for entry into the United States. For fiscal years 1985 through 1989,⁵ the sampling rates for cheese varied from 1.2 percent in fiscal year 1985 to 9 percent in fiscal year 1986, 3 percent in fiscal years 1987 and 1988, and 2.5 percent in fiscal year 1989.

In the past, we reported our concerns about FDA's low sampling rates for imported foods.⁶ Because FDA's sample selection is targeted to those products or importers with a history of violations, it is not representative of all products entering the United States and may not provide adequate coverage of all imported products. Although FDA believes that this approach to sampling is more efficient and effective given its available resources, it is also concerned that only a small portion of imports is physically inspected. FDA officials we talked to said that they would like to increase the level of inspection for all FDA-regulated imported foods, including cheese. New York district officials told us that they would like to double their current inspection coverage of imported food products; however, to do so they would need additional resources. In a 1990 report,⁷ FDA estimated that while the total number of imported food entries had more than tripled since the early 1970s, resources dedicated to these inspections had remained static. As a result, the percentage of import entries inspected by the agency had declined by over 50 percent during the same period. The Advisory Committee on the Food and Drug Administration, in its May 1991 final report, also emphasized its concern about the decrease in the level of FDA's import inspections compared with the growth in imports.

In addition to reporting on the low rates of sampling for imported products, we have identified other problems with FDA's import program. Some of the problems we have reported include FDA's lack of adequate enforcement authorities and inability to deter the distribution of contaminated imports. (See Related GAO Products for a list of reports.) According to FDA officials, because all imported foods are subject to the same inspection procedures, many of these concerns are also relevant to

⁵FDA was unable to provide us with data on the total number of entries of cheese into the United States for fiscal years 1990 and 1991; therefore, we could not determine what percentage of cheese entries were sampled for these years.

⁶Pesticides: Better Sampling and Enforcement Needed on Imported Food (GAO/RCED-86-219, Sept. 26, 1986).

Imported Foods: Opportunities to Improve FDA's Inspection Program (GAO/HRD-89-88, Apr. 28, 1989).

⁷The Efficiency of FDA Import Practices (Washington, D.C., Mar. 1990).

imported cheese. Both FDA headquarters and district officials told us that additional resources and enforcement authorities to strengthen FDA's general import inspection program would also result in better regulation of imported cheese. For example, according to New York district officials, FDA should have the authority to require the destruction of violative imports, such as contaminated cheese, that are a known health hazard, or at a minimum have the authority to stamp each box of the entry "Refused entry into the United States." They believe that such kinds of authority would provide better control over contaminated products.

Conclusions

Because cheese is susceptible to potentially fatal contamination and FDA does not have the authority to inspect foreign cheese manufacturing facilities, developing certification programs with exporting countries appears to be an effective method by which FDA can better regulate the safety of imported cheese. Certification programs, such as the one with France for soft cheese, allow FDA to supplement its own inspection efforts, by encouraging a foreign government to ensure that products exported to the United States are safe. In addition, we believe that certification agreements are a mechanism by which FDA can require foreign facilities to use good manufacturing processes similar to those required in the United States. However, certification agreements may become a mere paper exercise if they are not actively monitored by FDA. Without a formal program to monitor such agreements, FDA has no way of knowing what, if any, effect these agreements have had on the safety of imported products and whether they are truly providing the intended level of safety. Furthermore, given FDA's resource constraints and low sampling of imported products, proper monitoring of certification programs can provide FDA with information to better target these limited resources.

Recommendation

Because of the lack of information on the effectiveness of FDA's certification program with France, we recommend that the Secretary, HHS, direct the Commissioner, FDA, to develop a formal program to monitor the French certification agreement for imported soft cheese, as well as other certification programs, as appropriate.

Scope and Methodology

To obtain information on FDA's inspection procedures for imported cheese, we obtained documents and interviewed officials at FDA's Center for Food Safety and Applied Nutrition in Washington, D.C., and the Office of Regulatory Affairs in Rockville, Maryland. To obtain a district perspective,

we interviewed officials at FDA's New York and Los Angeles districts—the two largest import volume districts. To obtain information on the value and quantity of cheese imported into the United States, we reviewed foreign agricultural trade statistics developed by the U.S. Department of Agriculture from official data released by the Bureau of the Census. To determine FDA's sampling, testing, and detention rates for imported cheese, we reviewed data maintained in FDA's national data bases, including the Program Oriented Data System and the Import Detention System. We also reviewed data maintained in the New York district's Import Sample Tracking System and FDA's Laboratory Management System. We did not verify the reliability of the data because source documents were not available. We performed our work between October 1991 and May 1992 in accordance with generally accepted government auditing standards.

Views of Agency Officials

We discussed the information in this report with officials of FDA's Center for Food Safety and Applied Nutrition, Office of Regulatory Affairs, and Office of General Counsel. They generally agreed with the facts as presented. Where appropriate, changes have been made on the basis of these discussions to further clarify the information presented. As requested by your office, we did not obtain written agency comments on a draft of this report.

As arranged with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this letter. At that time, we will send copies to the Secretary of Health and Human Services and to the Commissioner of FDA. We will also make copies available to others upon request.

This review was conducted under the direction of John W. Harman, Director, Food and Agriculture Issues, who may be reached at (202) 275-5138. Other major contributors to this report are listed in appendix I.

Sincerely yours,



J. Dexter Peach
Assistant Comptroller General

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Related GAO Products

Pesticide Monitoring: FDA's Automated Import Information System Is Incomplete (GAO/RCED-92-42, Dec. 31, 1991).

International Food Safety: Comparison of U.S. and Codex Pesticide Standards (GAO/PEMD-91-22, Aug. 22, 1991).

Imported Foods: Opportunities to Improve FDA's Inspection Program (GAO/HRD-89-88, Apr. 28, 1989).

ADP Systems: FDA Can Reduce Development Risks for Its Import Information System (GAO/IMTEC-88-42, Sept. 30, 1988).

Pesticides: Better Sampling and Enforcement Needed on Imported Food (GAO/RCED-86-219, Sept. 26, 1986).

Pesticides: FDA's Investigation of Imported Apple Juice Concentrate (GAO/RCED-86-214FS, Aug. 29, 1986).

Imported Wines: Identifying and Removing Wines Contaminated With Diethylene Glycol (GAO/RCED-86-112, Mar. 4, 1986).

Legislative Changes and Administrative Improvements Should Be Considered for FDA to Better Protect the Public From Adulterated Food Products (GAO/HRD-84-61, Sept. 26, 1984).

Better Regulation of Pesticide Exports and Pesticide Residues in Imported Food Is Essential (CED-79-43, June 22, 1979).

Food and Drug Administration's Program for Regulating Imported Products Needs Improving (HRD-77-72, July 5, 1977).